AMERICAN FEED INDUSTRY ASSOCIATION

March 21, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 88N-0038 (Records and Reports Concerning Experience With Approved New Animal Drugs)

Dear Food and Drug Administration:

These comments are submitted by the American Feed Industry Association (AFIA), which is the national, not-for-profit trade association representing the manufacturers of more than 70% of the primary formula livestock and poultry feed sold in the United States. AFIA also represents manufacturers and distributors of a variety of animal health products, including Type A medicated articles intended for use in manufacturing medicated feed and other new animal drugs. AFIA members also include businesses that supply ingredients, equipment, and services to the feed manufacturing industry.

AFIA applauds FDA's decision to remove medicated feed manufacturers from the scope of the interim final rule. In light of the fundamental change from product specific medicated feed applications to establishment-wide feed mill licenses stemming from the enactment of the Animal Drug Availability Act of 1996, we agree with FDA's decision, as stated in the rulemaking preamble, that any remaining issues regarding records and reports for medicated feed manufacturers must be addressed in a new proposed rule, if necessary.

If FDA decides to proceed with such a rulemaking, AFIA strongly recommends that three day field alert reports for licensed feed mills be limited to those product and manufacturing defects that may result in serious adverse drug events. The limitation to product and manufacturing defects that may result in serious adverse drug events, a concept embodied by FDA in the recently published interim final rule for NADA sponsors, is a major improvement on the 1991 proposed rule, which would have applied the three day reporting requirement to any manufacturing or product defect.

FDA's new approach is consistent with the thrust of AFIA's July 1992 comment, which urged the agency to focus on the reporting of problems with drug-related human food safety or animal safety ramifications. AFIA's earlier comment noted that the vast majority of product complaints received by AFIA member firms are not related to any added medication in the feed; rather, they relate to purported defects such as "too many fines," bad appearance, unpalatable feed,

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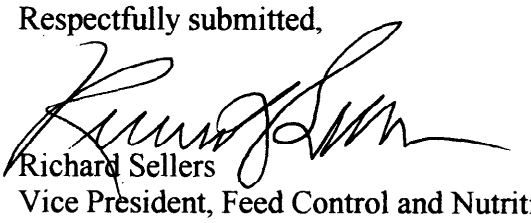
off-color, or bad odor. Upon reviewing complaints, it is generally straightforward for a feed manufacturer to conclude that a purported product defect of this nature is not one that may result in a serious adverse drug event. If FDA concludes it is necessary to proceed with a reproposal regarding records and reports for licensed feed mills, it should follow this new approach. Removing product and manufacturing defects of this type from the scope of the three day reporting requirements would eliminate much unnecessary paperwork, thereby helping to conserve both industry resources and scarce agency resources.

AFIA appreciates this opportunity to comment.

Respectfully submitted,



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